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DOC 930009

FINAL

DATA EVALUATION REPORT

TREO TM SPF 15, 3-Way Protecting Lotion

Study Type: Acute Oral Toxicity in Rats

Prepared for:

Health Effects Division
Office of Pesticide Programs
Environmental Protection Agency
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DATA EVALUATION REPORT

STUDY TYPE: Guidelines 81-1 and 152-10: Acute oral toxicity in rats

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901
MRID Number: 421513-04

TEST MATERIAL: TREO TM SPF 15, 3-way protecting lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Laboratories, Inc., 950 Third Avenue, New York, NY

STUDY NUMBER: 90033-3

TESTING FACILITY: Consumer Product Company, Inc., 12 Spielman Road, Fairfield, NJ

TITLE OF REPORT: Acute Oral Toxicity in Rats

AUTHOR: Steven Nitka

STUDY COMPLETED: February 23, 1990

CONCLUSIONS: The acute oral LD_{50} for TREO TM SPF 15, 3-way protecting lotion was greater than 5 g/kg (the limit dose for an acute oral study) in male and female rats.

CORE CLASSIFICATION: Core Supplementary, using Guideline requirements 81-1 and 152-10. This study can be upgraded pending submission of the: (1) purity and stability data on the test material and other possible ingredients in the lotion; 2) body weights at day 7; and 3) the number of animals housed per cage.

TOXICITY CATEGORY: IV--Caution

A. MATERIALS

1. Test Material

Test material: TREO TM SPF 15, 3-way protecting lotion
Purity: Not reported
Physical description: Lotion
Lot number: Not reported
Storage conditions: Not reported
Stability: Not reported
Specific gravity: 1.03

2. Controls

Animals: None needed
Test substance: None needed

3. Test Animals

Species: Rat
Strain: Wistar albino
Source: Not stated. The study author indicated that animals were ordered from a suitably licensed dealer.
Sex: Male and female
Numbers: Five males and five females
Housing: Stainless steel cages (The number of animals/cage was not indicated).
Identification: Ear clips
Acclimation: Seven days
Age: Six to nine weeks
Weight at exposure: 212-226 g (males), 204-236 g (females)
Feeding: Feed (Agway ProLab Rat, Mouse and Hamster 1000 Feed) and water provided ad libitum
Selection: By weight

4. Exposure

Route of administration: Oral gavage
Dose level: 5 g/kg

B. TEST PERFORMANCE

All animals were fasted 18 hours before treatment. The test article was used as received. Five rats per sex received a single oral dose of 5 g/kg of TREO TM SPF-15, 3-way protecting lotion by gavage. Individual doses were calculated on the basis of body weight. The dose was administered using a stainless steel intragastric feeding needle. Food and water were provided to all rats following administration of the test material. Clinical observations were made 1, 3, 6, and 24 hours postdosing and at least once daily for a 2-week observation period. Each animal was weighed shortly before treatment and on day 14. All animals were subjected to gross necropsy.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No deaths occurred. Based on these results, the acute oral LD_{50} for TREO TM SPF-15, 3-way protecting lotion in male and female rats was greater than 5 g/kg. All rats appeared normal throughout the 14-day

observation period and gained weight by day 14. No gross changes were observed at necropsy.

D. QUALITY ASSURANCE MEASURE

A signed Quality Assurance Statement was presented, but not dated. A Good Laboratory Practice compliance statement was included.

E. REVIEWERS' COMMENTS

The acute oral LD_{50} for TREO TM SPF-15, 3-way protecting lotion in male and female rats was greater than 5 g/kg, the limit dose for an acute oral toxicity study. Based on these results, the Toxicity Category for TREO TM SPF-15, 3-way protecting lotion is IV--Caution.

This study was classified as Core Supplementary, according to Guideline Series 81-1 and 152-10, because purity and stability data were not reported. In addition, the number of animals housed per cage was not specified. The source from which the animals were obtained was not reported; therefore, it cannot be verified if the animals were obtained from a reputable dealer. Also, body weight data were not reported after week 1; they were only reported at the beginning and end of the study. This study can be upgraded pending submission of this information.

The reviewers note that the Quality Assurance Statement was signed, but not dated.